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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/869,540	06/27/2001	Masaaki Mori	56001(46342)	4354
21874	7590	06/14/2004	EXAMINER	
EDWARDS & ANGELL, LLP P.O. BOX 55874 BOSTON, MA 02205			JIANG, DONG	
			ART UNIT	PAPER NUMBER
			1646	
DATE MAILED: 06/14/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action**

Application No.

09/869,540

Applicant(s)

MORI ET AL.

Examiner

Dong Jiang

Art Unit

1646

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 28 April 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY** [check either a) or b)]

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.  
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.  
2. ☒ The proposed amendment(s) will not be entered because:  
(a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);  
(b) ☐ they raise the issue of new matter (see Note below);  
(c) ☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
(d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet.

3. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.  
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).  
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.  
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.  
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

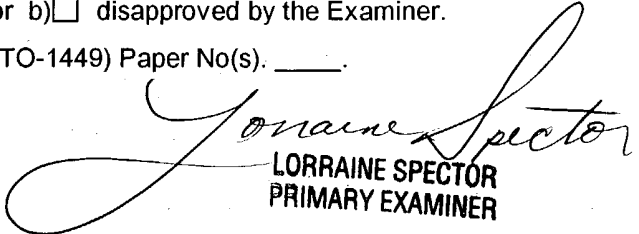
Claim(s) allowed: \_\_\_\_\_

Claim(s) objected to: \_\_\_\_\_

Claim(s) rejected: 1, 2 and 12-14.

Claim(s) withdrawn from consideration: \_\_\_\_\_

8. ☐ The drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.  
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.  
10. ☐ Other: \_\_\_\_\_

  
LORRAINE SPECTOR  
PRIMARY EXAMINER

Continuation of 2. NOTE: the newly amended claim 2 recites "which comprises a solution of .. and a buffer", which renders the claim indefinite as it is unclear whether the buffer is a part of the "solution", and what is the interrelationships between the elements, which must be explicitly stated in a kit claim.

Continuation of 5. does NOT place the application in condition for allowance because:

The declaration under 37 CFR 1.132 filed on 28 April is insufficient to overcome the prior art rejections of claims 1, 2 and 12-14 based upon the Ames, Maratos-Flier, Bolton, and Salon references as set forth in the last Office action because of insufficient evidence for the following reasons:

The declaration by Masaaki Mori presents experimental data to demonstrate that the derivatized MCH, MCH(2-19), MCH(3-19), MCH(4-19), and MCH(5-19) exhibit the agonist activity, and that, with the exception of MCH(4-19), the agonist activity of MCHs derivatized is reduced compared to that of MCH (full length). The derivatized MCH(4-19) showed higher agonist activity than that of both full length MCH, and full length derivatized MCH, which is concluded in the declaration as unexpected result. However, it is noted that an important control is missing in the experiment presented in the declaration, i.e., the underivatized MCH(2-19), MCH(3-19), MCH(4-19), and MCH(5-19) were not included in the assay. This is particularly important because without such, the conclusion cannot be drawn as the possibility exists that the underivatized MCH(2-19), MCH(3-19), MCH(4-19), and MCH(5-19) may have the similar profile of agonist activity to that of the derivatized counterparts, and the underivatized MCH(4-19) may possess comparable or higher agonist activity than that of the full length underivatized MCH. Applicants "unexpected result" indicates that the agonist activity of each agent, derivatized or underivatized, is not predictable, and the burden is on applicants to show the evidence with the proper control that the derivatized MCH(4-19) is indeed an exception in comparison to others listed with respect to their agonist activity.

Applicant's argument regarding the prior rejection of the claims under 35 USC 103 filed on 28 April 2004 has been fully considered, but is not deemed persuasive for the reasons of record, and for the reasons below.

Applicants argue that no combination of the references teaches or suggests the use of iodinated MCH derivative MCH(4-19) in assays to screen compounds, nor provides motivation to prepare such an agent. This argument is not persuasive because as addressed in the previous Office Actions, although the reference do not teach the specific MCH(4-19), the reference by Maratos-Flier teaches the minimal functional sequence of MCH, i.e., MCH(5-15), and thus, any MCH fragment comprising this sequence, such as MCH(4-15), would be obvious to be functional. Applicants file a declaration indicating that the derivatized MCH(4-19) has unexpected higher agonist activity than that of other derivatized MCHs. However, the declaration is insufficient to overcome the prior art rejections of the present claims for the reasons addressed above.